

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 - EXPEDITED PROCEDURE

Serial Number: 09/912,270

Filing Date: July 24, 2001

Title: CARBON DIOXIDE AS AN AID IN PASTEURIZATION

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REMARKS

This responds to the Office Action mailed on December 1, 2004.

Claims 1, 2, and 21 are amended, and claim 20 is canceled; as a result, claims 1, 2, 12-19, and 21 are now pending in this application.

Support for the amendments to claims 1 and 2 can be found in the specification at page 9, lines 14-19. No new matter is added by the amendments.

I. The Rejections under 35 U.S.C. §102(e)

Claims 1, 2, 12-15, 18 and 19 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kato et al. Claims 1, 2, and 12-14 were rejected under 35 USC § 102(e) as being anticipated by Kawakami et al. These rejections are respectfully traversed.

The present invention provides a process to reduce or inhibit the growth of bacteria and other pathogens in a liquid, comprising adding CO₂ into the liquid via sparging, wherein the concentration of CO₂ in the liquid is from about 400-2000 ppm, thermally inactivating the bacteria and other pathogens in the liquid, wherein the added CO₂ cooperates to increase the efficacy of the thermal inactivation process, and removing the free CO₂ from the liquid upon completion of the thermal inactivation process by application of a vacuum.

The present invention further provides a process to enhance the efficacy of thermal inactivation of pathogens in a liquid, comprising adding CO₂ to the liquid via sparging, wherein the concentration of CO₂ in the liquid is from about 400-2000 ppm, thermally processing the liquid, wherein the added CO₂ cooperates with the thermal inactivation process so that the death rate of bacteria and other pathogens in the liquid is increased over the death rate that occurs during thermal inactivation carried out in the absence of added CO₂, and removing the free CO₂ from the liquid upon completion of the thermal inactivation process by application of a vacuum.

In order to anticipate a claim, "a reference must disclose every element of the challenged claim, and enable one skilled in the art to make the anticipating subject matter." *PPG Industries Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 37 U.S.P.Q.2d 1618 (Fed. Cir. 1996). A single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F. 2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). An

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assertion that the claimed invention was described in the prior art may be overcome by showing that the disclosure of the prior art reference cited as anticipating a claimed invention lacks the characteristics of the claimed invention. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Kato et al. provide a process for making a fermented soybean milk and a fermented soybean milk product. The process disclosed in Kato et al. involves the steps adding glucose to filtered soymilk, sterilizing the milk, cooling the milk to 38°C, adding yeast and lactic acid bacteria, allowing the microorganisms to ferment the milk for 15 hours at 38°C, heating the milk at 125°C for 10 seconds to stop the fermentation and to stop the biological activity of the bacteria and yeast, subjecting the milk to a vacuum chamber at 200 mmHg to evacuate alcohol and CO₂.

In contrast, Applicants' claims are directed to a process to inhibit the growth of bacteria in a liquid and to enhance the efficacy of thermal inactivation processing. As amended, Applicants' claimed process recites sparging CO₂ into the liquid so that the concentration of CO₂ in the liquid is from about 400-2000 ppm. The CO₂ is added to the liquid prior to thermal inactivation of the bacteria, and then the excess free CO₂ is removed from the liquid after the thermal inactivation step by application of a vacuum.

The Examiner is respectfully requested to note that the present claims recite the step of "sparing CO₂ into the liquid." Sparging is defined as agitating (a liquid) by means of compressed air or gas entering through a pipe (Merriam-Webster Online Dictionary). Kato et al. do not disclose or suggest the addition of exogenous CO₂ to a liquid by sparging. Instead, the CO₂ in the liquid of Kato et al. is a product of the fermentation process.

Additionally, Kato et al. do not disclose the quantity of CO₂ present in the liquid prior to sterilization. As amended, claims 1 and 2 of the present invention recite that the concentration of CO₂ in the liquid is from about 400-2000 ppm. As Kato et al. do not sparge the CO₂ into the liquid and do not quantify the amount of CO₂ in the liquid, the Kato et al. patent does not anticipate claims 1, 2, 12-15, 18 and 19. Therefore, withdrawal of the §102(e) rejection under Kato et al. with respect to claims 1, 2, 12-15, 18 and 19 is appropriate, and is respectfully requested.

Kawakami et al. provide a reducing-sugar containing fat emulsion for IV administration and a method of sterilizing such an emulsion. Kawakami et al. dissolve CO₂ into the emulsion

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by establishing a CO₂ plenum within the preparation tank containing the emulsion until the emulsion attains the objective pH (see col. 6, lines 47-49). In the Examples, Kawakami et al. disclose that the emulsion is pressurized with CO₂ prior to sterilization (col. 8, lines 61-67) and that the top space of the tank is pressurized with CO₂ prior to sterilization of the emulsion (col. 9, lines 61-63 and see col. 11, lines 16-18).

According to the method of Kawakami et al., the CO₂ gas thereby dissolved in the emulsion is removed passively (i.e., gradually released during and after the sterilization procedure) or with a CO₂ gas absorber at the end use point. (See col. 7, lines 1-5 (gradual release); col. 3, lines 32-34; col. 7, lines 23-35 (gas absorber).) The CO₂ gas absorbers disclosed in Kawakami et al. for use with their method include soda lime products, which are combinations of calcium hydroxide and sodium hydroxide, and may contain potassium hydroxide.

Kawakami et al. do not disclose or suggest the addition of CO₂ to a liquid by sparging. Additionally, Kawakami et al. do not provide the quantity of CO₂ present in the liquid prior to sterilization. Kawakami et al. also do not disclose the removal of CO₂ present in the liquid after sterilization by application of a vacuum. As Kawakami et al. do not sparge the CO₂ into the liquid, do not quantify the amount of CO₂ added to the liquid, and do not remove the CO₂ present in the liquid after sterilization by application of a vacuum, the Kawakami et al. patent does not anticipate claims 1, 2, 12-15, 18 and 19. Therefore, withdrawal of the §102(e) rejection under Kawakami et al. with respect to claims 1, 2, 12-15, 18 and 19 is appropriate, and is respectfully requested.

II. The Rejections under 35 U.S.C. §103

Claims 15-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawakami et al. Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Kato et al. or Kawakami et al. (as applied above). These rejections are respectfully traversed.

A rejection of obviousness under 35 U.S.C. § 103 requires that the Examiner establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner

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has the burden to establish three basic elements. First, the Examiner must establish that there is some suggestion or motivation, either in the cited documents themselves or in the knowledge generally available to an art worker, to modify the documents or to combine document teachings so as to arrive at the claimed invention. Second, the Examiner must establish that there is a reasonable expectation of success. Finally, the Examiner must establish that the prior art documents teach or suggests all the claim elements. M.P.E.P. § 2143. Applicants respectfully submit that the claims are not *prima facie* obvious in view of the cited documents because the cited documents do not teach or suggest all of the claim limitations.

With respect to claims 15-17, there is no suggestion or motivation in Kawakami et al. to modify Kawakami et al.'s method for producing sterile emulsions for IV administration in order to arrive at Applicants' processes to inhibit the growth of bacteria in juice, milk or another dairy product, and to enhance the efficacy of a thermal inactivation process of these liquid products. Moreover, Kawakami et al. do not teach or suggest sparging CO₂ into milk or other dairy products prior to thermal inactivation, so that the concentration of CO₂ in the milk or other dairy product is from about 400-2000 ppm. Kawakami et al. also do not teach or suggest removing the excess free CO₂ from the liquid after thermal inactivation by application of a vacuum. Accordingly, because Kawakami et al. do not teach or suggest all of the elements of claims 15-17, withdrawal of the rejection of the claims under 35 U.S.C. § 103 is appropriate and is respectfully requested.

With respect to claim 19, there is no suggestion or motivation in Kato et al. or Kawakami et al. to modify the respective methods in order to arrive at Applicants' processes to inhibit the growth of bacteria in a dairy product or juice that contains a flavoring agent, and to enhance the efficacy of a thermal inactivation process of such flavored liquids. Kato et al. and Kawakami et al. do not teach or suggest sparging CO₂ into such liquids prior to thermal inactivation, so that the concentration of CO₂ in the liquid containing a flavoring agent is from about 400-2000 ppm. Accordingly, because Kawakami et al. and Kato et al. do not teach or suggest all of the limitation of claim 19, withdrawal of the rejection of claim 19 under 35 U.S.C. § 103 is appropriate and is respectfully requested.

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Dkt: 1153.011US1**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612) 349-9580 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this May day of 2005.

Name

Signature